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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,322

03/27/2008

Lydie Bougueleret

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NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.
400 TECHNOLOGY SQUARE
CAMBRIDGE, MA 02139

EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,322	Applicant(s) BOUGUELERET ET AL.	
	Examiner Padma V. Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/ Restriction

- 1 Applicants preliminary amendment filed on 12/20/05 has been entered.
Claims 1-19 are pending in the application.
2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I claim(s) 1 -7 (in part) and 8-9 (in part) drawn to and an isolated polypeptide CPP and a method of screening for and/or diagnosis of a cardiovascular disorder in a subject, comprising the steps of detecting and/or quantifying the level of Cardiovascular disorder Plasma Polypeptide (CPP) SEQ.ID.NO:1.

Group II claim(s) 1 -7 (in part) drawn to a method of screening for and/or diagnosis of a cardiovascular disorder in a subject, comprising the steps of detecting and/or quantifying the level of Cardiovascular disorder Plasma Polypeptide (CPP).

(Further restriction to one SEQ.ID.NO: 2-7 /CPP is required , see paragraph # 4)

Group III , claim(s) 8-9 (in part) and 14 (in part) drawn to an isolated polypeptide comprising the amino acid sequence.

(Further restriction to one SEQ.ID.NO: 2-7 /CPP is required , see paragraph # 4)

Group IV claim(s) 10 (in Part) and 11-13 drawn to CPP antibody that selectively binds to a polypeptide comprising the amino acid sequence SEQ.ID.NO:1-7 and a method of binding an antibody to said CPP comprising contacting the antibody with a biological sample.

(Further restriction to one SEQ.ID.NO 1-7 /CPP is required , see paragraph # 4)

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Group V claim(s) 14 drawn to a method of treatment or prophylaxis using polypeptide.

Use claim 14 has been treated as method claim .

(Further restriction to one SEQ.ID.NO 1-7 /CPP is required , see paragraph # 4)

Group VI claim(s) 15 drawn to a method of treatment or prophylaxis using antibody.

Use claim 15 has been treated as a method claim.

(Further restriction to one SEQ.ID.NO 1-7 /CPP is required , see paragraph # 4)

Groups VII claim(s) 16- drawn to a method of identifying CPP polypeptide modulator

(Further restriction to one SEQ.ID.NO: 1-7 /CPP is required , see paragraph # 4)

Groups VIII claim(s) 17-18 drawn to a method of identifying a modulator of a cardiovascular disorder comprising the steps of administering s candidate agent and detecting and quantifying polypeptide.

(Further restriction to one SEQ.ID.NO: 1-7 /CPP is required , see paragraph # 4)

Groups IX claim(s) 19 drawn to a method for monitoring the efficacy of a treatment of a subject having or at risk of developing a cardiovascular disorder with an agent, the method comprising obtaining a pre-administration biological sample from the subject prior to administration of the agent and detecting and/or quantifying the level of at least polypeptide in the biological sample.

(Further restriction to one SEQ.ID.NO: 1-7 /CPP is required , see paragraph # 4)

3. The technical feature of linking Groups 1- IX appears to be that they all relate to polypeptides and antibodies and methods using polypeptides and antibodies .

Pursuant to 37 C.F.R.\$ 1.475 (d), the ISA/US considers that where multiple products, processes and methods are claimed, the main invention shall consists of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly the main invention is claim(s) 1 -7 (in part) and 8-9 (in part) SEQ.ID.NO:1.

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Further pursuant to 37 C.F.R.1.475 (d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention. Therefore, the groups of inventions II-IX do not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention.

DISTINCT INVENTIONS

4. Polypeptides SEQ.ID.NO : 1-7 share no common special technical feature because the polypeptides have no common structure (i.e., no common sequence) and they each perform a different function in that each elicit an antibody that specifically binds to that polypeptide. Thus they share no common structure and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among polypeptides SEQ.ID.NO : 1-7 or antibodies that bind to polypeptides SEQ.ID.NO : 1-7.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Please note: Customer Number 75074 is associated with the address of record for is NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC , 400 TECHNOLOGY SQUARE, CAMBRIDGE, MA 02139. However, the power of attorney is given to Customer Number 01095. Therefore, applicant is requested to clarify these issues.

8. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives

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transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 156, 191. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571) 272-0956.

Respectfully,

/Padma V Baskar/

Examiner, Art Unit 1645

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645